# Commitment to the Creation of Sustainable Influenza Vaccine Production Capacity Worldwide

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# Program Goals

1. Help to develop and sustain influenza vaccine production capacity at the national level for individual country/grantee.
2. Assist with obtaining investment necessary for commercial scale production so that individual countries can become regional suppliers.
3. Achieve sustainable influenza vaccine production capacity worldwide.

# Why HHS/ASPR/BARDA?

**HHS/ASPR/BARDA is uniquely positioned to lead an effort to build sustainable influenza vaccine production capacity worldwide.**

- **Technical and contractual expertise**
- **Defined relationships with multinational pharmaceutical companies**
- **Developed non-profit and international partnerships**

# Partnership with WHO

**In support of international pandemic preparedness, BARDA has supported the accelerated development and production of influenza vaccine for the non-US population during FY 2006-2009, with a total of $28 million provided through cooperative agreements with WHO to Vietnam, Thailand, Indonesia, India, Mexico Brazil, Egypt, Romania, Russia and Serbia. WHO has independently funded Korea and Iran.**

# Partnership with WHO

- **HHS funding to WHO addresses global and country-specific needs for pilot scale influenza vaccine production, with the goal of preparing countries for eventual commercial scale manufacturing of influenza vaccines.**

- **HHS funding to WHO is used for training, laboratory equipment, manufacturing process development, development and validation of product release assay methods, clinical sample analysis, pilot lots, scale-up development for vaccine manufacturing, and vaccine production equipment.**

# Partnership with PATH

**In FY 2009, an additional $7.9 million was awarded to PATH through a cooperative agreement to be carried out in collaboration with Vietnam. These funds will support development of GMP CTM for phase 1 and 2 safety and immunogenicity human clinical trials with vaccine produced in Vietnam.**

# Point-of-Care Test Collaboration for International Capacity Building

- Collaboration with NIAID and CDC
- Expanded clinical evaluation of a rapid test to detect Influenza A and B antigens, and distinguish H1, H3, H5 Influenza A subtypes
- An investigational device (developed with NIAID, CDC-BARDA funding)
- Enables assessing potential use in other clinical studies and settings
- Supported by South East Asian Influenza Clinical Research Network (SEAICRN) through NIAID.
- Also coordinated with a CDC-sponsored clinical study at International Center for Diarrheal Disease Research in Bangladesh (ICDDR,B)

# International Capacity Building
# Total Financial Commitment : $40.4 million

- **FY 2005** $1 million ASPR funding to Vabiotech-Vietnam
- **FY 2006** $10 million of emergency supplemental funding to WHO; sub-granted to India, Indonesia, Vietnam, Thailand, Mexico & Brazil
- **FY 2007** Funding requested in annual budget; not appropriated
- **FY 2008** $14.4 million of annual funding to WHO; sub-granted to six original grantees plus Egypt, Serbia and Romania (WHO independently funds Iran and Korea)
- **FY 2009** $3.6 million to WHO; sub-granted to Russia's Institute for Experimental Medicine; plus $7.9 million to PATH; and $3.5 for rapid diagnostics to support clinical trials

# Measuring Progress

- **Measuring progress is key to ensuring continued financial commitment from donors and investors**
  - Development of a reporting matrix to track the progress of each of our grantees as well as progress toward our overall programmatic goal
- **Funding**
  - For 2010, an $11 million spend plan is under development
  - Working to quantify and qualify the resource needs for the life of the project
  - Working with WHO to determine infrastructure investment needed for success of each individual grantee as well as the overall programmatic goal of worldwide capacity
  - **How to identify additional donors and/or investors?**

# Critical Components From Core Committee Meeting - August 17, 2009

In order to successfully build sustainable capacity, the following must be considered simultaneously:

- Incentives to attract trained workforce to countries/regions;
- Training and development of workforce capacity;
- Willingness and opportunity to transfer technology;
- Market research and development, including demand for and uptake of manufactured biologics;
- Verification and characterization of the disease burden;
- Development of enhanced Regional/National Regulatory Authorities;
- Public health policy on the use of seasonal and pandemic influenza vaccines;
- Planning and conduct of appropriately designed clinical trials;
- Government support of manufacturing facilities.

# Sustainability

- As capacity is built, sustainability of the program is interlinked with continued availability of resources, including funding and expertise.
- A model of sustainability for such technologies or platforms in developing countries is also important to consider.
- For influenza vaccines, the development of seasonal vaccine production capacity is viewed as a primary logical method that could allow for pandemic surge vaccine production capacity.
- To sustain worldwide capacity, ensuring seasonal demand for the vaccine is critical.

# The Case for Investment

- **The case for investment in the building of regionally-based independent and sustainable vaccine production capacity abroad can be emphasized through:**
  - A match to current policy objectives;
  - Long-term development impact;
  - The gains to national security strategy and health diplomacy initiatives;
  - Commitment to multilateral framing of issues;
  - Commitment to responsible and effective foreign investment; and
  - Development of health care distribution capability.

# A Technology Toolbox

- The portfolio or tool chest of available technologies and product options should focus on both short- and long-term approaches.
- An additional element that could be helpful is the creation and/or support of a vaccine development toolbox of manufacturing technologies, laboratory methods, reference reagents, reference standards as well as procedures and documentation templates.
- BARDA will host a meeting focused specifically on this developing such a technical toolbox of options in early 2010.

# Other Considerations

- Missed goal of having enough vaccine for target groups in time both in US and abroad. How can we solve this? Newer technologies, expanding production in developing countries, or some combination thereof?
- Should we focus on a single disease, such as influenza, or would public health needs could be better served by a focus on a set of diseases, including influenza?
- Need for adequate, sustained funding. The intense yet shifting focus on a variety of disease areas can have a detrimental effect on the overall system. One initiative, such as pandemic influenza, may have an intense focus for a few years, until a new issue arises and focus and resources are shifted.
- To deal effectively with emerging diseases in the twenty-first century, a comprehensive approach that addresses all emerging infectious disease is needed

# Conclusion

- **Specific answers HHS/BARDA program hopes to obtain from this workshop:**
  - What resources should a country have, or be willing to make available, to attract US investment, either bilaterally or through other entities?  Should there be minimum requirements?
  - **What is the best investment for the available funds?**